

K082753



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NOV 24 2008

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510(k) SUMMARY

Contact: Manfred Th. Plaumann

Date prepared: September 10, 2008

Trade or proprietary name: Futurabond M/Futurabond M *Single Dose*

Classification name: Agent, Tooth Bonding Resin (872.3200)

Predicate devices:

| | |
|--|---------|
| Clearfil S ³ Bond | K042913 |
| Clearfil S ³ Bond Single Dose | K051796 |

Device description: Futurabond M/Futurabond M *Single Dose* is a single-component, light-curing, self-etch-bond reinforced with nano-particles to build a durable bond between tooth substance and light-curing filling materials without marginal leakage.

Futurabond M/Futurabond M *Single Dose* displays the same adhesive properties of total-etch preparations without separate etching of the tooth substance.

Futurabond M/Futurabond M *Single Dose* tolerates residual moisture.

Futurabond M/Futurabond M *Single Dose* is an all-purpose adhesive for use with all light-curing composites, compomers andOrmocer[®]s.

Futurabond M/Futurabond M *Single Dose* is offered in 5 ml plastic bottles (Futurabond M) and in 0.06 ml *Single Dose* blisters (Futurabond M *Single Dose*).

Intended use:



- Futurabond M/Futurabond M *Single Dose* is suited as adhesive for direct restoration with light-curing filling materials in all cavity classes.
- Futurabond M/Futurabond M *Single Dose* is also suited for cavity sealing as a pretreatment for indirect restorations
- Futurabond M/Futurabond M *Single Dose* is also suited for the treatment of exposed root surfaces
- Futurabond M/Futurabond M *Single Dose* can be used for core build-ups using light-cured or dual-cured filling materials.

Technological characteristics: All of the components of **Futurabond M/Futurabond M Single Dose** are found in the legally marketed devices K042913 (Clearfil S³Bond), K051796 (Clearfil S³Bond Single Dose) and K051463 (Xeno Adhesive with Activator). **Futurabond M** and **Futurabond M Single Dose** are identical in composition and performance characteristics.

The prior use of all of the components of **Futurabond M/Futurabond M Single Dose** in legally marketed devices supports our decision that additional testing for cytotoxicity and mutagenicity as well as additional biocompatibility studies with the final formulation are not necessary.

We believe that the prior use of the components of **Futurabond M/Futurabond M Single Dose** in legally marketed devices and the performance data and results provided support the safety and effectiveness of **Futurabond M/Futurabond M Single Dose** for the intended use.

VOCO GmbH, September 10, 2008


Manfred Th. Plaumann  VOCO GmbH
(Managing Board) Ron-Plattner-Str. 1-3
27472 CUXHAVEN
Germany



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Thorsten Gerkensmeier
VOCO GmbH
Anton-Flettner-Strasse 1-3
Cuxhaven, Germany D- 27472

NOV 24 2008

Re: K082753
Trade/Device Name: Futurabond M/Furabond M Single Dose
Regulation Number: 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: September 17, 2008
Received: September 19, 2008

Dear Dr. Gerkensmeier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu S. Lin, Ph.D.", with a stylized flourish at the end.

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K082753

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Prescription Use X

OR

Over-The-Counter Use

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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